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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,291	04/12/2001	Peter Krammer	4121-122	4237

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05/30/2003

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/834,291

Applicant(s)

KRAMMER ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 May 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 1,2,4,5,13 and 14.

Claim(s) objected to: _____.

Claim(s) rejected: 6-11,15-26.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: The amendments to the claims add limitations that are not encompassed within the scope of the claims previously examined. For example, claims 6, 10, 15, 17, 18 and 20 add the limitation of measuring the level of expression of a reporter gene or CD95 receptor DNA. Thus, examination of the claims would require a new search.

In addition, claims 8 and 11 raise new grounds for rejection under 35 U.S.C. §112, second paragraph. The claims are now directed to a method which comprises an assay or wherein influence takes place on the basis of an assay. The term "assay" is extremely broad and the specification provides no guidance with respect to how the assay should be comprised within the method or in what way influence is based on an assay. Claim 11 is also indefinite in the recitation of "influence", which lacks antecedent basis in the amended claim 10.

Continuation of 3. Applicant's reply has overcome the following rejection(s): Rejection of claims 6-9 and 15-22 under 35 U.S.C. §112, first paragraph, as lacking enablement for reasons set forth in Paper No. 18 is withdrawn. The rejection was made based on the absence of guidance regarding which expression construct would be operative in the claimed method. Upon further consideration, it is apparent that the ability of a tumor cell to undergo apoptosis in response to a chemotherapeutic agent would only in rare circumstances be dependent upon the identity of the expressible sequence linked to the isolated CD95 receptor promoter region. That is, the ability of the tumor cell to undergo apoptosis is already inherent to the cell, particularly in view of the fact that the cell would already comprise a CD95 receptor promoter region linked to a proapoptotic sequence (i.e., CD95). Therefore, the expression construct is, in most cases, irrelevant to practicing the method..

Continuation of 5. does NOT place the application in condition for allowance because: Claims 6-9 and 15-22 stand rejected under 35 U.S.C. §112, first paragraph, because the claims as amended add new matter. In response to the rejection of record, Applicant argues that the originally filed specification sets forth all of the process steps in the claimed method. Applicant argues that it is sufficient if the originally filed disclosure would have conveyed to one of ordinary skill that applicants had possession of what is claimed. Applicant concedes that the method steps are not disclosed in the exact order set forth in the claims, but that Applicants are not required to show an exact example for each method claim. Applicant argues that the Office must present evidence or reasons why persons skilled in the art would not consider the description sufficient.

First, it should be clarified that the rejection does not assert that the method steps are not present in the application. The basis of the rejection is that the disclosure does not set forth each of the method steps in a single method, and therefore does not contemplate the method that is claimed. This is clearly indicated on page 10 of the previous office action which states, "[m]ethods comprising the method steps as set forth in the amended and new claims do not appear anywhere in the original disclosure. In particular, the originally filed disclosure does not describe a method wherein an expression vector comprising the p53 binding region of the claims is introduced into a tumor cell and the cell is assayed for cell death" (emphasis added).

Applicant seems to be arguing that the presence or absence of method steps and the order of those method steps are irrelevant to a description of the method. That, once method steps are set forth in a specification, Applicant can claim any new combination of those method steps. In other words, a recitation of method steps adequately describes all methods that comprise those steps. This is akin to arguing that a recitation of car parts adequately describes a car. Clearly this is not the case. The originally filed disclosure does not contemplate a method comprising introducing an expression vector comprising the p53 binding region into a cell and assaying for cell death. Thus, the disclosure fails to describe critical elements of the claimed method, i.e., the composition and order of the process steps that make up the claimed method. Therefore, the claims stand rejected..



JAMES KETTER
PRIMARY EXAMINER